

REQUEST FOR RECALCULATION OF PATENT TERM ADJUSTMENT IN VIEW OF WYETH*

Attorney Docket Number: 101288-1P US	Patent Number: 7,625,908
Filing Date (or 371(b) or (f) Date): January 17, 2007	Issue Date: December 1, 2009
First Named Inventor: Laurent Francois Andre HENNEQUIN	
Title: QUINAZOLINE DERIVATIVES	

PATENTEE HEREBY REQUESTS RECALCULATION OF THE PATENT TERM ADJUSTMENT (PTA) UNDER 35 USC 154(b) INDICATED ON THE ABOVE-IDENTIFIED PATENT. THE PATENTEE'S SOLE BASIS FOR REQUESTING THE RECALCULATION IS THE USPTO'S PRE-WYETH INTERPRETATION OF 35 U.S.C. 154(b)(2)(A).

Note: This form is only for requesting a recalculation of PTA for patents issued before March 2, 2010, if the sole basis for requesting the recalculation is the USPTO's pre-Wyeth interpretation of 35 U.S.C. 154(b)(2)(A). See Instruction Sheet on page 2 for more information.

Patentees are reminded that to preserve the right to review in the United States District Court for the District of Columbia of the USPTO's patent term adjustment determination, a patentee must ensure that he or she also takes the steps required under 35 U.S.C. 154(b)(3) and (b)(4) and 37 CFR 1.705 in a timely manner.

**Wyeth v. Kappos*, No. 2009-1120 (Fed. Cir., Jan. 7, 2010).

Signature /Gregory T. Lowen/	Date January 29, 2010
Name (Print/Typed) Gregory T. Lowen	Registration Number 46,882
Note: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required in accordance with 37 CFR 1.33 and 11.18. Please see 37 CFR 1.4(d) for the form of the signature. If necessary, submit multiple forms for more than one signature, see below*.	
<input checked="" type="checkbox"/> *Total of <u>1</u> forms are submitted.	

The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 12 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re PATENT APPLICATION of: Laurent Francois Andre Hennequin <i>et al.</i>) Confirmation No. 3653
)
Application No.: 10/578,663) Group Art Unit: 1624
)
Filed (371(c) Date): January 17, 2007)
)
Patent No.: 7,625,908)
)
Issued: December 1, 2009) Examiner: Truong, Tamthom Ngo
)
FOR: QUINAZOLINE DERIVATIVES)

Date: **January 29, 2010**

**REQUEST FOR RECONSIDERATION OF PATENT TERM ADJUSTMENT
UNDER 37 C.F.R. § 1.705(b) and (d) FOR FAILURE TO ADD FURTHER
TERM ADJUSTMENT UNDER § 1.702(b)**

This Request for Reconsideration of Patent Term Adjustment (PTA) is being filed pursuant to 35 U.S.C. § 154(b) and 37 C.F.R. §§ 1.702 - 1.705, and requests that an additional **187** days of patent term adjustment be added to the **200** days of patent term adjustment accorded US Patent 7,625,908 on the first page thereof, for a total of **387** days as detailed below.

This Request is being concurrently filed with the US PTO form entitled "Request for Recalculation of Patent Term Adjustment in View of Wyeth" because the Request for Reconsideration raises PTA issues beyond Wyeth.

The Request for Reconsideration is timely filed under 37 C.F.R. § 1.705(d), being within two months of the December 1, 2009 date on which US Patent 7,625,908 issued. Applicant agrees with the US PTO calculation of 181 days of "**A Delay**" that was stated in the Notice of Allowance. The present request is for reconsideration of (1) the subsequent failure of the US PTO to appropriately account for the "**B Delay**" when calculating the final patent term adjustment, which was first indicated in the Issue Notification; and (2) the 19 additional days PTA that were inexplicably afforded to the application in the Issue Notification. Therefore, the issues raised by this Request for Reconsideration could not have

been raised prior to payment of the Issue Fee, and is appropriately and timely raised under 37 C.F.R. § 1.705(d) at this time.

Transmitted herewith is deposit account authorization for payment of the \$200 fee set by 37 C.F.R. § 1.18(e). The statement of facts supporting this Request as required by 37 C.F.R. § 1.705(b)(2) is presented below.

STATEMENT OF FACTS UNDER 37 C.F.R. § 1.705(b)(2)

This Statement of Facts will track the required content for the Statement of Facts as itemized in subparagraphs (i) through (iv) of 37 C.F.R. § 1.705(b)(2).

- (i) **The correct patent term adjustment and the basis or bases under § 1.702 for the adjustment; and**
 (ii) **The relevant dates as specified in §§ 1.703(a) through (e) for which an adjustment is sought and the adjustment as specified in § 1.703(f) to which the patent is entitled.**

The following Table and the accompanying Notes “a” through “e” detail both (i) the correct patent term adjustment and the basis therefore; and (ii) the relevant dates from §§ 1.703(a) - (e) and the adjustment as specified in § 1.703(f) to which the patent is entitled. As used herein, the term “**A Delay**” refers to the days of US PTO delay in excess of the times specified in 37 C.F.R. § 1.702(a); and “**B Delay**” or “**B Period**” refers to the period after a date 3-years from National Stage Commencement until patent grant, as specified in 37 C.F.R. § 1.702(b), and clarified by the Director’s Notice Concerning Calculation of the Patent Term Adjustment under 35 U.S.C. 154(b)(1)(B) dated September 9, 2009. [See also note b below].

Event	Event Date	A Delays	B Delays	Applicant Delays
National Stage Commenced	9-May-06			
371 Completion Date	17-Jan-07			
14-Months from 371 Completion Date	17-Mar-08	A ↓		
First Action on Merits	12-Sep-08	↓ 179 ^a		
Response to Non-Final Action	12-Dec-08			
4-Months from Applicant’s Response	12-Apr-09	↓		
Mail Final Rejection	14-Apr-09	↓ 2 ^a		
3-Years from National Stage Commencement*	9-May-09			
Response to Final Rejection	20-May-09			
Notice of Allowance Mailed	10-Jul-09		B	
Issue Fee Paid	9-Oct-09			
Patent Grant	1-Dec-09		↓ 206 ^b	
Totals		181	206	0 ^c

PTA Calculation Per Wyeth Decision:				
PTO-A Period Total		181		
PTO-B Period Total		206		
Minus A/B Overlap Per Wyeth Decision		0 ^d		
Minus Applicant Days		0		
PTA Per Wyeth Decision (181 + 206)		387		
Erroneous PTA as Printed on Issued Patent:				
PTO-A Days Per Notice of Allowance		181		
Additional Time of Unknown Origin		19 ^g		
Minus Applicant Days		0		
Erroneous PTA Printed on Issued Patent (181 + 19)		200		
Additional PTA Per Wyeth (387) over PTA Printed on Issued Patent (200)		187		

Footnote a: Under 37 C.F.R. § 1.702(a)(1) and § 1.703(a)(1) there is a **179-day “A Delay”** (from March 17, 2008 to September 12, 2008), being the number of days in the period beginning on the day after the date that is fourteen months after the date on which the application fulfilled the requirements of 35 U.S.C. § 371 (March 17, 2008) and ending on the date of an action under 35 U.S.C. § 132 (September 12, 2008). There is also a **2-day “A Delay”** (from April 12, 2009 to April 14, 2009) being the number of days in the period beginning on the day after the date that is four months after the date on which Applicant filed a response to an action under 35 U.S.C. § 132 (April 12, 2009) and ending on the date a final action under 35 U.S.C. § 132 was mailed (April 14, 2009).

Footnote b: Under 37 C.F.R. § 1.702(b) and § 1.703(b) there is a **206-day “B Delay”** (from May 9, 2009 to December 1, 2009), being the number of days in the period beginning on the day after the date that is three years after the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) in an international application (May 9, 2009) and ending on the date a patent was issued (December 1, 2009) [there are no periods of exclusion under 37 C.F.R. § 1.702(b)(1-5) or § 1.703(b)(1-4) that are here applicable]. This is consistent with the Director’s September 9, 2009 “Notice Concerning Calculation of the Patent Term Adjustment under 35 U.S.C. § 154(b)(1)(B) involving International Applications Entering the National Stage Pursuant to 35 U.S.C. § 371,” acknowledging that under 35 U.S.C.

154(b)(1)(B), an applicant is entitled to additional patent term adjustment if the issue of an original patent is delayed due to the failure of the USPTO to issue a patent within three years after the actual filing date of the application [May 9, 2006 plus three years = May 9, 2009], whereas previously the US PTO's computer program incorrectly calculated the three-year pendency provision of this statute in international applications as being measured from the date that all the requirements of 35 U.S.C. § 371 were fulfilled. **If the US PTO computer program has not yet been corrected, this Request for Reconsideration additionally includes a request that the Director's September 9, 2009 Notice be applied to correctly calculate the "B Delay" in this Application.**

Footnote c: Under 37 C.F.R. § 1.704 (a) and (b) there are **0 days of Applicant delay.**

Footnote d: Under 37 C.F.R. § 1.703(f) there are **0 days of overlap** of periods of delay, being the period during which both "**A Delay**" and "**B Delay**" were simultaneously accruing.

Footnote e: In the Issue Notification, the US PTO inexplicably added 19 days of PTA to the 181 days of PTA previously indicated on the Notice of Allowance for a total of 200 days PTA. This 19 days is of unknown origin as it does not appear to be linked to either "**A Delay**" time or "**B Delay**" time. It appears that the 19 days may then simply be an error by the US PTO.

As indicated the above Table, Applicant is entitled to a Patent Term Adjustment comprising all 181 days of "**A Delay**" plus all 206 days of "**B Delay**" minus the **0** days of Applicant delay, or $181 + 206 - 0 = 387$ days.

(iii) Whether the patent is subject to a terminal disclaimer and any expiration date specified in the terminal disclaimer.

US Patent 7,625,908 is not subject to a terminal disclaimer.

(iv)(A) Any circumstances during the prosecution of the application resulting in the patent that constitute a failure to engage in reasonable efforts to conclude processing or examination of such application as set forth in § 1.704.

There were no circumstances during the prosecution of the application resulting in the patent that constitute a failure to engage in reasonable efforts to conclude processing or examination of such application as set forth in § 1.704.

(iv)(B) That there were no circumstances constituting a failure to engage in reasonable efforts to conclude processing or examination of such application as set forth in § 1.704.

There were no circumstances constituting a failure to engage in reasonable efforts to conclude processing or examination of such application as set forth in § 1.704.

DISCUSSION

Applicant Agrees With the Preliminary Patent Term Adjustment Determined As of the Mailing Date of the Notice of Allowance

Applicant agrees with, and therefore did not contest, the US PTO preliminary calculation of 181 days of Patent Term Adjustment as set forth in the Notice of Allowance, which calculation was made before the issue date of the patent was set. This Patent Term Adjustment of 181 days, as of the date the Notice of Allowance which was mailed on July 10, 2009, is comprised of:

- **181 days of “A Delay” (between the periods of March 17, 2008 and September 12, 2008; and between April 12, 2009 and April 14, 2009)**

37 C.F.R. § 1.702(a)(1) provides that the term of a patent shall be adjusted if issuance of the patent was delayed due to the failure of the US PTO to mail either a notification under 35 U.S.C. § 132 (an Action) or a Notice of Allowance within 14 months after filing of the application (here, the § 371 date). The present application has a § 371 date of January 17, 2007, but the first Action was not mailed until September 12, 2008. Thus, pursuant to §1.703(a)(1), Applicant is entitled to a patent term adjustment for each day of the period between 14 months after Applicant’s § 371 date (March 17, 2008) and the mailing date of the first Action (September 12, 2008), or 179 days.

37 C.F.R. § 1.702(a)(2) provides that the term of a patent shall be adjusted if issuance of the patent was delayed due to the failure of the US PTO to respond to a reply under 35

U.S.C. § 132 or to an appeal taken under 35 U.S.C. § 134 not later than four months after the date on which the reply was filed or the appeal was taken. In the present application, Applicant filed a response to a notification under 35 U.S.C. § 132 on December 12, 2008 but the US PTO did not mail a subsequent notification until April 14, 2009. Thus, pursuant to §1.703(a)(2), Applicant is entitled to a patent term adjustment for each day of the period between 4 months after Applicant's response filing date (April 12, 2009) and the mailing date of the subsequent Action (April 14, 2009), or 2 days. These 2 days are added to the 179 days of other "A Delay" time to provide a total "A Delay" time of 181 days.

- **0 days of Applicant Delay**

There were no days of Applicant delay under 37 C.F.R. § 1.704 as of the June 17, 2009 mailing date of the Notice of Allowance.

Accordingly, the total period of adjustment under 37 C.F.R. § 1.703(f), as of the mailing date of the Notice of Allowance was correctly stated in the Notice of Allowance as being **181 days**.

**Applicant Disagrees With the US PTO
Calculation of the Final Patent Term Adjustment
Indicated in the Issue Notification and Patent Grant**

The Issue Notification mailed November 11, 2009 set December 1, 2009 as the issue date for US Patent 7,625,908, and noted that the Patent Term Adjustment was 200 days. This Patent Term Adjustment of 200 days was also noted on the patent grant. It is respectfully submitted that this final Patent Term Adjustment of 200 days is in error.

While the calculation resulting in the final Patent Term Adjustment of 181 days apparently properly takes into account the 181 days of "A Delay", it fails to properly account for the 206 days of US PTO "B Delay" accrued during the "B Period" beginning after the 3-year-from-filing date of May 9, 2009 and continuing to the date the patent issued on December 1, 2009. Thus, subsequent to the Notice of Allowance, the US PTO should have

recalculated the Patent Term Adjustment reported in the Issue Notification to take into account any additional **“A Delay”** occurring after the Notice of Allowance, any **“B Delay”** (in that it could not be calculated until the issue date was fixed), and reducing the total US PTO delay by any overlap of the **“A Delay”** with the **“B Delay”**, and further reduce that total by any additional Applicant delay to determine the final Patent Term Adjustment to be accorded the patent.

- **19 days of additional US PTO Delay after Notice of Allowance**

In the Issue Notification, the US PTO inexplicably added 19 days of PTA to the 181 days of PTA previously indicated on the Notice of Allowance, for a total of 200 days PTA. This 19 days is of unknown origin as it does not appear to be linked to either **“A Delay”** time or **“B Delay”** time. It appears that the 19 days may then simply be an error by the US PTO that requires correction.

- **206 days of B Delay between May 9, 2009 and December 1, 2009**

In addition to the **“A Delay”** discussed above, 35 U.S.C. § 154(b)(1)(B) and 37 C.F.R. § 1.702(b) provide for an additional adjustment of the term of the patent of 206 days, which is the number of days attributable to the failure of the US PTO to issue a patent within three years after the actual filing date of the application (US national stage commencement for this International Application). As confirmed by the Director's September 9, 2009 Notice, 37 C.F.R. § 1.702(b) provides that the term of a patent shall be adjusted if issuance of the patent was delayed due to the failure of the US PTO to issue the patent within three years after the application filing date, here the date on which the national stage commenced under 35 U.S.C. § 371(b) or (f) in an international application. The present application entered the U.S. national stage on May 9, 2006 but the subject patent did not grant until December 1, 2009. Thus, pursuant to §1.703(b), Applicant is entitled to a patent term adjustment for each day of the period between May 9, 2009 (the day three years from the filing date of the application) and December 1, 2009, or 206 days of **“B Delay”**.

- **0 days of Applicant Delay, either before or after the Notice of Allowance**

Since there was no Applicant delay after the Notice of Allowance (and none before), there is no reduction of the period of patent term adjustment for delays calculated under section 1.703 for any time during which the applicant failed to engage in reasonable efforts to conclude prosecution of the application under section 1.704.

37 C.F.R. § 1.703(f) provides that the term of a patent entitled to adjustment under § 1.702 and this section shall be adjusted for the sum of the periods calculated under paragraphs (a) through (e) of this section, *to the extent that such periods are not overlapping*, less the sum of periods calculated under § 1.704. Thus, as applicable here, the total period of Patent Term Adjustment, when appropriately calculated, is the total of **181 days of “A Delay”** plus **206 days of “B Delay”** minus **0 days of Applicant delay**, for a total Patent Term Adjustment of $181 + 206 - 0 = 387$ days. However, because of the erroneous interpretation of 35 U.S.C. § 154(b)(1)(B) by the US PTO and the inexplicable addition by the US PTO of 19 days (as discussed above), the Patent Term Adjustment accorded this patent in the Issue Notification and on the face of the granted patent is only 200 days.

Therefore, Applicant respectfully requests that US Patent 7,625,908 be accorded an additional **187 days** (206 days of non-overlapping “**B Delay**” time minus 19 days of inexplicably accorded time) of Patent Term Adjustment pursuant to 37 C.F.R. § 1.702(b) in addition to the **200 days** of Patent Term Adjustment already afforded to this patent in the Issue Notification and patent grant, for a total Patent Term Adjustment pursuant to 37 C.F.R. § 1.703(f) of **387 days**.

The Director is hereby authorized by this paper to charge any additional fees which may be required by reason of this Request for Reconsideration, or credit any overpayment to Deposit Account 50-0310.

Respectfully Submitted,
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